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FORMULATION AND EVALUATION OF MOUTH DISSOLVING FILM OF POLMACOXIB

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Abstract
Mouth dissolving films (MDFs) have emerged as a promising drug delivery system for improving patient compliance and enhancing bioavailability of poorly soluble drugs. The present research work focuses on the formulation and evaluation of mouth dissolving films of Polmacoxib, a selective cyclooxygenase-2 (COX-2) inhibitor belonging to Biopharmaceutics Classification System (BCS) Class II. Polmacoxib exhibits poor aqueous solubility, which limits its dissolution rate and oral bioavailability. The objective of the study was to formulate rapidly dissolving oral films capable of enhancing dissolution and providing rapid onset of action.
Mouth dissolving films were prepared using the solvent casting method employing Hydroxypropyl Methylcellulose (HPMC) and Polyvinyl Alcohol (PVA) as film-forming polymers. Polyethylene glycol 400 and glycerol were used as plasticizers, while mannitol and aspartame served as sweetening agents. Citric acid was incorporated as a saliva-stimulating agent. The prepared formulations were evaluated for physicochemical characteristics including thickness, weight variation, folding endurance, surface pH, wetting time, drug content uniformity, disintegration time, and in-vitro drug release.
The optimized formulation demonstrated satisfactory mechanical properties, rapid disintegration, acceptable surface pH, and enhanced drug release profile. In-vitro dissolution studies indicated rapid release of Polmacoxib from the film matrix compared to conventional dosage forms. FTIR studies confirmed compatibility between the drug and excipients. The findings suggest that mouth dissolving films represent an effective and patient-friendly approach for delivering Polmacoxib with improved dissolution and therapeutic efficacy.
Keywords: Mouth dissolving films, Polmacoxib, COX-2 inhibitor, solvent casting, oral thin films, bioavailability enhancement.

1. INTRODUCTION

Drug delivery systems have witnessed remarkable progress over the past few decades, evolving from conventional dosage forms toward advanced and patient-friendly approaches designed to improve therapeutic efficacy and patient compliance. Among the various routes of drug administration, the oral route remains the most preferred due to its convenience, cost-effectiveness, ease of manufacturing, and high patient acceptance. Conventional oral dosage forms such as tablets and capsules are widely used; however, they are associated with several limitations including delayed onset of action, poor bioavailability, extensive first-pass metabolism, gastrointestinal degradation, and swallowing difficulties, particularly in pediatric, geriatric, and dysphagic patients. These drawbacks often reduce therapeutic effectiveness and patient adherence to medication regimens.
To overcome these limitations, fast dissolving drug delivery systems have emerged as innovative alternatives to conventional oral formulations. Among these systems, Mouth Dissolving Films (MDFs), also known as oral thin films, have gained significant attention in recent years due to their rapid disintegration, ease of administration, improved patient compliance, and enhanced bioavailability. MDFs are thin, flexible polymeric films designed to dissolve or disintegrate rapidly when placed on the tongue or oral mucosa, releasing the drug directly into the saliva for absorption. Because of their rapid dissolution behavior, MDFs can provide faster onset of therapeutic action compared to traditional dosage forms.
Mouth dissolving films possess several advantages that make them highly suitable for modern drug delivery applications. These include rapid onset of action, improved patient convenience, ease of administration without water, accurate dosing, enhanced portability, reduced risk of choking, and better patient compliance. Furthermore, drugs incorporated into MDFs may partially bypass hepatic first-pass metabolism through buccal or sublingual absorption, thereby improving systemic bioavailability. Due to these advantages, MDF technology has become an attractive platform for delivering drugs requiring rapid therapeutic response.

The formulation of MDFs generally involves the use of hydrophilic film-forming polymers such as Hydroxypropyl Methylcellulose (HPMC), Polyvinyl Alcohol (PVA), pullulan, sodium alginate, and maltodextrin. These polymers contribute to film formation, flexibility, and rapid hydration. In addition, plasticizers such as polyethylene glycol and glycerol are incorporated to improve elasticity and prevent brittleness. Sweetening agents, flavoring agents, saliva stimulants, and surfactants are also added to enhance palatability, mouthfeel, and drug release characteristics. The solvent casting method is one of the most widely used techniques for preparing MDFs due to its simplicity, cost-effectiveness, and ability to produce uniform films with consistent drug distribution.

Polmacoxib is a novel selective cyclooxygenase-2 (COX-2) inhibitor used in the treatment of osteoarthritis, musculoskeletal disorders, and inflammatory pain conditions. Unlike conventional non-steroidal anti-inflammatory drugs (NSAIDs), Polmacoxib exhibits selective inhibition of the COX-2 enzyme, thereby reducing inflammation and pain while minimizing gastrointestinal side effects associated with COX-1 inhibition. In addition, Polmacoxib demonstrates a unique dual mechanism involving carbonic anhydrase binding, which contributes to its pharmacological effectiveness and improved therapeutic profile.

Despite its therapeutic advantages, Polmacoxib exhibits poor aqueous solubility and belongs to the Biopharmaceutics Classification System (BCS) Class II category, characterized by low solubility and high permeability. In BCS Class II drugs, dissolution is the rate-limiting step for absorption, resulting in delayed onset of action and reduced oral bioavailability. Therefore, improving the dissolution behavior of Polmacoxib is essential for enhancing its therapeutic efficacy and achieving rapid pain relief.

Mouth dissolving film technology offers a promising strategy to overcome these challenges by incorporating Polmacoxib into a hydrophilic polymeric matrix capable of rapid hydration and dissolution. The large surface area and thin structure of MDFs facilitate rapid drug release and improved dissolution rate, thereby enhancing bioavailability and therapeutic response. Additionally, the patient-friendly nature of MDFs makes them particularly suitable for individuals who experience difficulty in swallowing conventional dosage forms.

Therefore, the present study aims to formulate and evaluate mouth dissolving films of Polmacoxib using suitable hydrophilic polymers and excipients in order to improve its solubility, dissolution rate, bioavailability, and onset of therapeutic action. The developed formulation is expected to provide an effective, convenient, and patient-compliant alternative to conventional oral dosage forms for the management of pain and inflammation.

2. NEED OF STUDY

Polmacoxib is a selective COX-2 inhibitor with promising anti-inflammatory and analgesic activity. Despite its therapeutic advantages, its poor aqueous solubility significantly limits dissolution rate and oral bioavailability. Conventional dosage forms of Polmacoxib may exhibit delayed onset of action and inconsistent absorption. Patients requiring immediate pain relief may not achieve rapid therapeutic response using traditional tablets or capsules.

Mouth dissolving films provide an opportunity to overcome these limitations by:

- Enhancing dissolution through hydrophilic polymer matrices
- Providing rapid drug release
- Improving patient compliance
- Reducing swallowing difficulties
- Offering convenient administration without water

Limited research has been conducted on Polmacoxib mouth dissolving films, thereby creating a research gap in this area. Hence, the present work was undertaken to develop and evaluate an optimized MDF formulation of Polmacoxib.

3. AIM AND OBJECTIVES

Aim

To formulate and evaluate mouth dissolving films of Polmacoxib.

Objectives

- To formulate mouth dissolving films using suitable polymers.
- To improve solubility and dissolution rate of Polmacoxib.
- To evaluate films for physicochemical parameters.

- To study in-vitro drug release profile.
- To optimize the best formulation for improved bioavailability.

4. MATERIALS AND METHODS

Materials

The following materials were used in the formulation of mouth dissolving films:

Sr. No.	Material	Category
1	Polmacoxib	Drug
2	HPMC	Film-forming polymer
3	PVA	Film-forming polymer
4	PEG 400	Plasticizer
5	Glycerol	Plasticizer
6	Aspartame	Sweetener
7	Mannitol	Sweetener
8	Citric Acid	Saliva stimulant
9	Flavoring Agent	Flavor enhancer

Method of Preparation

Mouth dissolving films were prepared using the solvent casting method.

Procedure

1. Required quantity of HPMC and PVA was dissolved in distilled water.
2. Plasticizers such as PEG 400 and glycerol were added with continuous stirring.
3. Polmacoxib was dissolved separately and added to the polymeric solution.
4. Sweeteners, saliva stimulants, and flavoring agents were incorporated.
5. The solution was stirred to obtain a homogeneous mixture.
6. The resulting solution was cast onto a glass plate.
7. Films were dried at controlled temperature.
8. Dried films were peeled carefully and cut into uniform strips.

5. PREFORMULATION STUDIES

Organoleptic Properties

Polmacoxib was evaluated for color, odor, taste, and appearance.

Parameter	Observation
Color	White to off-white
Odor	Odorless
Taste	Bitter
Nature	Crystalline powder

Melting Point Determination

The melting point of Polmacoxib was found within the reported range of 160–165°C, indicating purity of the drug sample.

Determination of λmax

The UV spectrum of Polmacoxib was recorded in suitable solvent using UV spectrophotometer.

Parameter	Observation
λmax	254 nm

Calibration Curve

Standard solutions of Polmacoxib were prepared and analyzed spectrophotometrically at 254 nm.

The calibration curve showed linearity within the selected concentration range.

FTIR Compatibility Studies

FTIR analysis was carried out to determine compatibility between drug and excipients.

Characteristic peaks of Polmacoxib were retained in the formulation spectrum, confirming absence of significant drug-excipient interaction.

6. FORMULATION OF MOUTH DISSOLVING FILMS

Nine formulations (F1–F9) were prepared using varying concentrations of HPMC and PVA.

Formulation	HPMC	PVA	PEG 400	Glycerol
F1	Low	Low	Fixed	Fixed
F2	Medium	Low	Fixed	Fixed
F3	High	Low	Fixed	Fixed
F4	Low	Medium	Fixed	Fixed
F5	Medium	Medium	Fixed	Fixed
F6	High	Medium	Fixed	Fixed
F7	Low	High	Fixed	Fixed
F8	Medium	High	Fixed	Fixed
F9	High	High	Fixed	Fixed

7. EVALUATION OF MOUTH DISSOLVING FILMS

Physical Appearance

All formulations were visually evaluated for color, transparency, smoothness, and flexibility.

The films were found to be smooth, transparent, and flexible without cracks or air bubbles.

Thickness

Film thickness was measured using digital vernier caliper.

Formulation	Thickness (mm)
F1	0.18
F5	0.22
F9	0.26

Uniform thickness indicated proper casting and drying process.

Weight Variation

Uniformity in weight indicates proper distribution of polymer and drug.

Formulation	Average Weight (mg)
F1	48
F5	52
F9	56

Folding Endurance

Folding endurance reflects flexibility and mechanical strength.

Formulation	Folding Endurance
F1	110
F5	165
F9	220

The optimized formulation showed satisfactory folding endurance.

Surface pH

Surface pH of all films remained close to neutral, indicating absence of oral mucosal irritation.

Formulation	Surface pH
F1	**6.4**
F5	6.7
F9	6.8

Wetting Time

Rapid wetting is essential for fast disintegration.

Formulation	Wetting Time (sec)
F1	42
F5	34
F9	22

Drug Content Uniformity

Drug content analysis confirmed uniform distribution of Polmacoxib within the films.

Formulation	Drug Content (%)
F1	95.2
F5	98.1
F9	99.3

In-vitro Disintegration Time

The disintegration behavior of films was evaluated in simulated salivary conditions.

Formulation	Disintegration Time (sec)
F1	48
F5	32
F9	18

Rapid disintegration was attributed to hydrophilic polymers and saliva-stimulating agents.

In-vitro Drug Release

Drug release studies were carried out using dissolution apparatus.

Time (min)	F9 Drug Release (%)
2	42
5	68
10	89
15	97

The optimized formulation exhibited rapid and enhanced drug release.

8. DRUG RELEASE KINETICS

Drug release data were fitted into various kinetic models including:

- Zero-order kinetics
- First-order kinetics
- Higuchi model
- Korsmeyer–Peppas model

The optimized formulation followed non-Fickian diffusion mechanism, indicating combined effect of diffusion and polymer relaxation.

9. STABILITY STUDIES

Stability studies were performed according to ICH guidelines.

The optimized formulation was stored under accelerated conditions.

Parameter	Observation
Appearance	No significant change
Drug Content	Stable
Disintegration Time	Within limits
Drug Release	Maintained

The formulation remained stable throughout the study period.

10. RESULTS AND DISCUSSION

The present investigation was successfully carried out to formulate and evaluate mouth dissolving films (MDFs) of Polmacoxib using the solvent casting method. Different formulations containing varying concentrations of Hydroxypropyl Methylcellulose (HPMC) and Polyvinyl Alcohol (PVA) were prepared and evaluated for physicochemical properties, mechanical strength, disintegration behavior, and in-vitro drug release characteristics. The obtained results demonstrated that mouth dissolving film technology is an effective approach for improving the dissolution and therapeutic performance of poorly soluble drugs such as Polmacoxib.

Preformulation studies confirmed the suitability of Polmacoxib for formulation development. The drug was found to be a white to off-white crystalline powder with physicochemical characteristics matching standard reported values. The melting point was observed within the official range, indicating purity of the drug sample. UV spectrophotometric analysis showed maximum absorption (λmax) at 254 nm, which was selected for analytical estimation. The calibration curve demonstrated good linearity within the selected concentration range. FTIR compatibility studies revealed that the characteristic peaks of Polmacoxib remained unchanged in the optimized formulation, confirming the absence of significant drug–excipient interactions and indicating compatibility between the drug and selected excipients.

The prepared mouth dissolving films were visually evaluated for appearance, transparency, flexibility, and surface smoothness. All formulations were found to be smooth, transparent, flexible, and free from air bubbles or cracks. The satisfactory appearance of films indicated proper selection of polymers and suitable processing conditions during formulation development. Thickness and weight variation studies showed minimal variations among formulations, confirming uniform casting and even distribution of drug and excipients throughout the film matrix. Uniform thickness and weight are important for ensuring dose accuracy and reproducible drug release.

Mechanical strength and flexibility of the prepared films were assessed using folding endurance studies. All formulations exhibited satisfactory folding endurance values, indicating adequate flexibility to withstand handling and packaging without breaking. The presence of plasticizers such as PEG 400 and glycerol significantly improved elasticity and reduced brittleness of the films. Among all formulations, batch F9 showed maximum folding endurance, indicating superior mechanical strength and flexibility.

Surface pH studies demonstrated that all formulations possessed pH values close to neutral, suggesting compatibility with the oral mucosa and minimal risk of irritation during administration. Drug content uniformity studies confirmed homogeneous distribution of Polmacoxib throughout the films, with all formulations falling within acceptable limits. The optimized formulation exhibited the highest drug content uniformity, indicating efficient mixing and proper drug dispersion within the polymer matrix.

Wetting time and disintegration studies revealed rapid hydration and fast disintegration behavior of the prepared films. The hydrophilic nature of HPMC and PVA facilitated rapid absorption of saliva into the film matrix, while citric acid acted as a saliva-stimulating agent that further accelerated disintegration. Among all batches, formulation F9 exhibited the shortest disintegration time, indicating rapid drug release capability. Rapid disintegration is an essential property of mouth dissolving films because it contributes to faster onset of therapeutic action and improved patient compliance.

In-vitro dissolution studies demonstrated significantly enhanced drug release from the MDF formulations compared to conventional oral dosage forms. The rapid drug release may be attributed to the thin structure of the films, increased surface area, rapid hydration, and uniform dispersion of Polmacoxib within the hydrophilic polymer matrix. Formulation F9 showed maximum drug release within a short period, indicating superior dissolution performance among all formulations. The improved dissolution profile suggests that MDF technology can effectively enhance the bioavailability of poorly soluble BCS Class II drugs such as Polmacoxib.

The enhanced dissolution behavior observed in the optimized formulation may be attributed to several factors including the hydrophilic polymeric matrix, increased surface area of the film, rapid hydration, improved wettability, and uniform molecular dispersion of the drug. In addition, the incorporation of plasticizers and saliva-stimulating agents improved film flexibility, hydration, and dissolution characteristics.

Stability studies performed under accelerated conditions demonstrated that the optimized formulation remained physically and chemically stable throughout the study period. No significant changes were observed in

appearance, drug content, disintegration time, or drug release profile, indicating good stability of the formulation.

Overall, the results of the present investigation confirmed that mouth dissolving film technology is a promising and patient-friendly drug delivery system for Polmacoxib. The optimized formulation successfully improved dissolution behavior, rapid drug release, and potential bioavailability while maintaining satisfactory mechanical and physicochemical properties. Therefore, mouth dissolving films of Polmacoxib may serve as an effective alternative to conventional oral dosage forms for rapid management of pain and inflammation.

11. CONCLUSION

The present research work successfully focused on the formulation and evaluation of mouth dissolving films (MDFs) of Polmacoxib using the solvent casting method. The developed films were found to possess satisfactory physicochemical and mechanical properties including uniform thickness, acceptable weight variation, good folding endurance, surface pH near neutrality, rapid wetting, and fast disintegration characteristics. The formulations also demonstrated excellent flexibility and stability, indicating their suitability for oral administration.

Preformulation studies confirmed the purity and compatibility of Polmacoxib with the selected excipients, while FTIR analysis revealed the absence of significant drug–excipient interactions. The use of hydrophilic polymers such as Hydroxypropyl Methylcellulose (HPMC) and Polyvinyl Alcohol (PVA), along with suitable plasticizers and saliva-stimulating agents, played an important role in improving the film properties and enhancing the dissolution behavior of the drug.

Among all the prepared formulations, the optimized batch exhibited superior performance in terms of rapid disintegration, improved mechanical strength, and maximum in-vitro drug release. The enhanced dissolution profile observed in the optimized formulation may be attributed to the hydrophilic polymeric matrix, increased surface area of the films, rapid hydration, and uniform dispersion of Polmacoxib within the film structure. These factors collectively contributed to faster drug release and the potential for improved bioavailability and rapid onset of therapeutic action.

Since Polmacoxib is a poorly water-soluble BCS Class II drug, formulation into mouth dissolving films proved to be an effective strategy for overcoming dissolution-related limitations associated with conventional oral dosage forms. The developed MDF formulation offers several advantages such as ease of administration without water, improved patient compliance, reduced risk of choking, convenience in handling, and suitability for pediatric, geriatric, and dysphagic patients.

Overall, the findings of the study confirmed that mouth dissolving film technology represents a promising, patient-friendly, and effective drug delivery system for Polmacoxib. The formulation has significant potential to improve therapeutic efficacy, dissolution rate, bioavailability, and patient acceptability compared to conventional dosage forms.

Further research may be directed toward:

- In-vivo pharmacokinetic and bioavailability studies
- Taste masking and palatability enhancement
- Optimization for large-scale industrial manufacturing
- Clinical evaluation for therapeutic effectiveness
- Long-term stability studies according to ICH guidelines
- Exploration of advanced solubility enhancement techniques
- Commercial development of Polmacoxib mouth dissolving films for rapid pain management applications

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